657—8.7(272C) Continuing education requirements as a condition for license renewal.

8.7(1) *Continuing education program attendance*. Continuing education programs that carry the seal of the American Council on Pharmaceutical Education (ACPE) approved provider will automatically qualify for continuing education credit. Program attendance is mandated in order to receive credit unless it is a correspondence course ACPE approved. Non-ACPE provider programs must be submitted to the board office for consideration no later than the date of the program. The request shall be made on forms provided by the board office. Pharmacists who are continuing their formal education in health-related graduate programs may be exempted from meeting the continuing education requirements during the period of such enrollment. Applicants for this exemption must petition the board on forms provided by the board office. This regulation does not preclude the future possibility of relicensure examination.

8.7(2) *Continuing education unit required.* The nationally accepted measurement of continuing education is referred to as CEU (Continuing Education Unit) and will be the measurement employed by the board of pharmacy examiners. Ten contact hours of approved continuing education are equivalent to one CEU. The board of pharmacy examiners will require 3.0 CEU each renewal period.

8.7(3) *Continuing education program attendance certificate*.

a. An approved provider will be required to make available to individual pharmacists certificates that indicate successful completion and participation in a continuing education program.

The certificate will carry the following information:

1. Pharmacist's full name.
2. Pharmacist's license number.
3. Number of contact hours for program attended.
4. Date and place of continuing education program.
5. Name of the program provider.
6. An indicator of the type or category of continuing education program completed.

b. Pharmacists must retain certificates in their own personal files for four years.

8.7(4) *Continuing education program topics*. Effective July 1, 1991, all pharmacists are required to obtain a minimum of 50 percent of their required 3.0 continuing education units (CEUs) in ACPE-approved courses dealing with drug therapy including, but not limited to, topics such as adverse drug reactions, biotechnology, clinical monitoring and drug utilization review, disease state, drug delivery systems, drug information, drug interactions, drug product selection, drugs, medical compliance, new drugs, nuclear pharmacy, OTC therapeutics, pharmacology, pharmacokinetics, substance abuse, and general therapeutics.

8.7(5) *New license holders registered by examination.* After the initial license is issued, the new license holder is exempt from meeting CE requirements for the first license renewal. Regardless of when license is first issued, the new license holder will be required to obtain 30 contact hours (3.0 CEU) of CE credits prior to the second renewal.

8.7(6) *Reporting continuing education credits:*

a. Pharmacists are required to submit documentation on the renewal application form that the continuing education requirements prescribed by the board have been met. Documentation will include the total number of credits accumulated for the renewal period and a listing of the individual programs attended, dates of participation, credits awarded and approved providers.

b. The board may require pharmacists to submit the program attendance certificates for the programs stated on the renewal application.

c. Failure to receive the renewal application shall not relieve the pharmacist of the responsibility of meeting continuing education requirements.

8.7(7) *License status.*

a. Active license. Active license status applies to those who have met Iowa requirements for continuing education or to those who are residents of another state, licensed to practice pharmacy in that state, and have met the continuing education requirements of that state. Iowa registrants actively practicing in a state which does not have continuing education requirements must meet Iowa continuing education requirements. Pharmacists meeting the continuing education requirements of another state must provide documentation on the renewal application of their license status in that state.

b. Inactive license. Failure of a pharmacist to comply with the continuing education requirements during the renewal period will result in the issuance of a renewal card marked "inactive" upon submission of renewal application and fee. Reactivation of an inactive pharmacist license shall be accomplished by the appropriate method described below. Internship, in each instance where internship is mentioned below, will be in a pharmacy approved by the board. The pharmacist will be issued a temporary "intern" card specifying the condition of internship.

(1) An inactive pharmacist who wishes to become active and who has been actively practicing pharmacy during the last five years in a state which does not require continuing education shall submit proof of continued licensure in good standing in the state or states of such practice. The pharmacist shall also complete one of the following options:

1. Take and successfully pass the Iowa Drug Law Examination,
2. Complete 160 hours internship for each year the pharmacist was on inactive status (not to exceed 1,000 hours), or
3. Obtain one and one-half times the number of continuing education credits required under 8.7(2) for each renewal period the pharmacist was inactive.

(2) An inactive pharmacist who wishes to become active and who has not been actively practicing pharmacy during the past five years, and whose license has been inactive for not more than five years, shall complete one of the following options:

1. Successfully pass all components of the licensure examination as required in 657—2.10(155A),
2. Complete 160 hours internship for each year the pharmacist was on inactive status, or
3. Obtain one and one-half times the number of continuing education credits required under 8.7(2) for each renewal period the pharmacist was inactive.

(3) An inactive pharmacist who wishes to become active and who has not been actively practicing pharmacy for more than five years shall petition the board for reactivation of the license to practice pharmacy under one or more of the following options:

1. Successfully pass all components of the licensure examination as required in 657—2.10(155A);
2. Complete 160 hours internship for each year the pharmacist was on inactive status (not to exceed 1,000 hours); or
3. Obtain one and one-half times the number of continuing education credits required under 8.7(2) for each renewal period the pharmacist was inactive.

(4) An inactive pharmacist who wishes to become active and who has been actively practicing pharmacy during the last five years in any state or states which required continuing education during the last five years shall submit proof of continued licensure in good standing in the state or states of such practice.

8.7(8) *Relicensure examination.* Nothing in the above requirements would preclude the board from requiring an applicant for renewal to submit to a relicensure examination.

8.7(9) *Physical disability or illness.* The board may, in individual cases involving physical disability or illness, grant waivers of the minimum education requirements or extensions of time within which to fulfill the same or make the required reports. No waiver or extension of time shall be granted unless written application therefor shall be made and signed by the licensee and a physician licensed by the board of medical examiners. Waivers of the minimum educational requirements for physical disability or illness may be granted by the board for any period of time not to exceed one renewal period. In the event that the physical disability or illness upon which a waiver has been granted continues beyond the period of the waiver, the licensee must reapply for an extension of the waiver. The board may, as a condition of any waiver granted, require the applicant to make up a certain portion or all of the minimum educational requirements waived by such method as may be prescribed by the board.

8.7(10) *New license holders registered by reciprocity.* After the initial license is issued, the new license holder by reciprocity will be required to obtain 30 contact hours (3.0 CEU) of CE credits prior to the first renewal period.

This rule is intended to implement Iowa Code sections 147.10, 272C.2 and 272C.6.

657—8.8(155A) Prescription pickup locations. A licensed pharmacist shall not participate in any arrangement or agreement whereby prescriptions may be left at, picked up from, accepted by, or delivered to any place of business not licensed as a pharmacy. This shall apply to the prescription order blank and to the completed prescription medication container. Provided, however, that nothing in this rule shall prohibit a licensed pharmacist or a licensed pharmacy, by means of its employee or by use of a common carrier, from picking up prescriptions or delivering prescriptions at the office or home of the prescriber, at the residence of the patient, or at the hospital or medical care facility in which a patient is confined.

This rule is intended to implement Iowa Code sections 155A.13 and 155A.15.

657—8.9(155A,126) Unit dose dispensing systems.

8.9(1) *Definitions.*

a. Single unit package. A single unit package is one which contains one discrete pharmaceutical dosage form.

b. Unit dose package. A unit dose package is one which contains that particular dose of a drug ordered for the patient for one administration time. A unit dose package is not always a single unit package.

c. Unit of issue package. A unit of issue package is one which provides multiple units/doses attached to each other but separated in a card or specifically designed container.

d. Unit dose dispensing systems. Unit dose dispensing systems are those drug distribution systems determined by the board to be pharmacy based and which involve single unit, unit dose, or unit of issue packaging in a manner which helps reduce or remove traditional drug stocks from patient care areas and enables the selection and distribution of drugs to be pharmacy based and controlled.

8.9(2) *Packaging requirements.* Packaging for all nonsterile drugs stored and dispensed in single unit, unit dose, or unit of issue packages shall:

a. Preserve and protect the identity and integrity of the drug from the point of packaging to the point of patient administration.

b. When packaged by the manufacturer or distributor, be in accordance with federal Food and Drug Administration (FDA) requirements.

c. When in single unit and unit dose packages prepackaged by the pharmacy for use beyond 24 hours, be in accordance with board subrule 8.3(1).

d. When in containers used for packaging, be clean and free of extraneous matter when the dosage unit(s) are placed into the package.

8.9(3) *Labeling requirements*.

a. Labeling for single unit or unit dose packaging shall comply with the following:

(1) Doses packaged by the manufacturer or distributor shall be properly labeled according to federal Food and Drug Administration (FDA) requirements.

(2) Doses packaged by the pharmacy shall be properly labeled according to subrule 8.3(2) if used beyond a 24-hour period.

b. Labeling for unit of issue packages shall contain the following information:

(1) Name, strength, and expiration date of drug when the packages are utilized for floor stock in an institutional setting.

(2) Name and room or bed number of patient, name of prescribing practitioner, name and strength of drug, directions for use, and name and address of the dispensing pharmacy, when the packages are utilized for patients in an institutional setting. Room or bed number, the name of prescribing practitioner, and the name and address of the dispensing pharmacy is not required if this information appears on a medication administration record used by the institution.

(3) Unit of issue packages dispensed to patients on an out-patient basis or in a noninstitutional setting shall be considered prescription containers and shall be labeled in accordance with board subrule 8.14(1).

c. If a pharmacist selects a generically equivalent drug product for a brand name drug product prescribed by a practitioner, the label must identify the generic drug and may identify the brand name drug for which the selection is made. The dual identification allowed under this paragraph must take the form of the following statement on the label: "(generic name) Generic for (brand name product)".

8.9(4) *General procedures*. The following will apply when a unit dose dispensing system is employed:

a. The pharmacist shall be responsible for determining the classification for containers set by USP Standard 671 used by the pharmacy to repackage nonsterile drugs into single unit, unit dose, or unit of issue packaging. This classification shall be used to determine maximal expiration dating for repackaging set forth in board subrule 8.9(5).

b. Established written policies and procedures shall be available in the pharmacy for inspection by the board or its agents which:

(1) Specify the categories of drugs or drug dosage forms which will or will not be dispensed under the particular unit dispensing system employed.

(2) Specify the pharmacy's recall policy for drugs returned upon a particular manufacturer's or FDA recall.

c. Those drugs not dispensed under a unit dose dispensing system shall be dispensed in accordance with the packaging requirements of the federal Food and Drug Administration (FDA) and labeling requirements of board subrule 8.14(1).

8.9(5) *Expiration dating*. Expiration dating for nonsterile drugs repackaged by the pharmacy into single unit, unit dose, or unit of issue packages shall meet the following conditions:

a. Not exceed 90 days from the date of repackaging except as provided in board subrule 8.9(5)*"c."*

b. Not exceed the manufacturer's original expiration date.

c. May exceed 90 days from the date of repackaging provided that each of the following conditions are met:

(1) The container is classified according to USP Standard 671 as being Class A or Class B for oral solid dosage forms or is a tight container for liquid dosage forms.

(2) The container is light-resistant when the manufacturer has labeled the product "sensitive to light."

(3) The expiration date is not greater than 12 months.

d. Drugs or dosage forms having known stability problems are assigned an expiration date of less than 90 days or are not repackaged as determined by policies developed by the pharmacy.

8.9(6) *Return of drugs.* Drugs dispensed in single unit, unit dose, or unit of issue packaging in compliance with board subrules 8.9(1) to 8.9(5) may be returned to the pharmacy stock and reissued provided that:

a. The expiration dating information is retrievable and identifiable.

b. Drugs returned from unit of issue packaging are kept separate according to manufacturer's lot number and the pharmacy's repackaged expiration date unless the pharmacy's recall policy states that all lots of a drug will be returned upon recall. In this instance, drugs returned to stock shall be kept separate according to the pharmacy's repackaged expiration date as determined in board subrule 8.9(5).

c. The drugs were stored under proper storage conditions.

d. The drugs are returned to the pharmacy in the original packaging as when dispensed.

e. The pharmacy includes in their written policies and procedures the manner in which they will record or identify controlled substances returned.

This rule is intended to implement Iowa Code sections 126.10, 155A.2, 155A.4(2)*"f,"* and 155A.28.

657—8.10(155A) Legal status of prescriptions. Prescriptions issued in accordance with the provisions of Iowa Code section 155A.27 shall be valid as long as a prescriber/patient relationship exists. Once the prescriber/patient relationship is broken and the prescriber is no longer available to treat the patient or oversee the patient's use of a prescription drug, the prescription loses its validity and the pharmacist, on becoming aware of the situation, shall cancel the prescription and any remaining refills. Provided, however, that the pharmacist shall exercise prudent judgment based upon individual circumstances to ensure that the patient is able to obtain a sufficient amount of the prescribed drug to continue treatment until the patient can reasonably obtain the service of another prescriber and a new prescription can be issued.

657—8.11(155A,124) Pharmacy and prescription records. All records shall comply with all applicable state and federal laws and regulations.

This rule is intended to implement Iowa Code sections 124.301, 124.306, 124.307, 124.308, and 155A.27.

657—8.12 Reserved.

657—8.13(155A,126) Patient med paks.

8.13(1) *Definition*. Patient med pak. A patient med pak is a customized patient medication package prepared for a specific noninstitutionalized patient which comprises a series of immediate containers containing two or more prescribed solid oral dosage forms, each container being labeled with the time or the appropriate period for the patient to take its contents.

8.13(2) *Packaging requirements*. Packaging for all nonsterile solid oral dosage forms stored and dispensed in patient med paks shall:

a. Preserve and protect the identity and integrity of the drug from the point of packaging to the point of dispensing.

b. When in containers used for packaging, be clean and free of extraneous matter when the drugs are placed into the package.

8.13(3) *Labeling requirements*.

a. The patient med pak shall be labeled with the following:

(1) Name of patient;

(2) A separate identifying serial number for each of the prescription orders for each of the drug products contained therein;

(3) The name, strength, physical description or identification, and the total quantity of each drug product;

(4) The directions for use and cautionary statements, if any, contained in the prescription order for each drug product;

(5) The name of the prescriber of each drug product;

(6) The date of preparation of the patient med pak and the expiration date (expressed as "do not use beyond" date) assigned to the patient med pak;

(7) The name and address of the dispensing pharmacy.

b. If a pharmacist selects a generically equivalent drug product for a brand name drug product prescribed by a practitioner, the label must identify the generic drug and may identify the brand name drug for which the selection is made. The dual identification allowed under this paragraph must take the form of the following statement on the label: "(generic name) Generic for (brand name product)".

8.13(4) *Expiration dating (beyond-use dating).* Expiration dating for nonsterile drugs repackaged by the pharmacy into patient med paks shall meet the following conditions: not exceed 90 days from the date of repackaging except as provided in board subrule 8.9(5), paragraph *"c."*

8.13(5) *General procedures*. The following will apply when patient med paks are employed:

a. The pharmacist shall be responsible for determining the classification for containers set by USP Standard 671 used by the pharmacy to repackage nonsterile drugs into patient med paks.

b. Drugs dispensed to patients in patient med paks may not be returned to the pharmacy stock and reissued.

c. In addition to any individual prescription filing requirements, a record of each patient med pak shall be made and filed. Each record shall contain, as a minimum:

(1) Name and address of patient;

(2) The serial number for each prescription order which is part of the med pak;

(3) The date of preparation of the patient med pak and the expiration date that was assigned;

(4) The name or initials of the pharmacist who prepared the patient med pak.

d. There are no special exemptions for patient med paks from the requirements of the Poison Prevention Packaging Act.

e. Customized patient medication packages prepared for institutionalized patients shall be in accordance with board subrules 8.9(1) to 8.9(6).

This rule is intended to implement Iowa Code sections 126.10, 155A.2, 155A.4(2)*"f,"* and 155A.28.

657—8.14(155A) Prescription label requirements.

8.14(1) The label affixed to or on the dispensing container of any prescription dispensed by a pharmacy pursuant to a prescription drug order shall bear the following:

a. Serial number (a unique identification number of the prescription);

b. The name and address of the pharmacy;

c. The name of the patient, or if such drug is prescribed for an animal, the species of the animal and the name of its owner;

d. The name of the prescribing practitioner;

e. The date the prescription is dispensed;

f. The directions or instructions for use, including precautions to be observed;

g. Unless otherwise directed by the prescriber, the label shall bear the brand name, or if there is no brand name, the generic name of the drug dispensed, the strength of the drug, and the quantity dispensed. If a pharmacist selects a generically equivalent drug product for a brand name drug product prescribed by a practitioner, the prescription container label must identify the generic drug and may identify the brand name drug for which the selection is made. The dual identification allowed under this paragraph must take the form of the following statement on the drug container label: "(generic name) Generic for (brand name product)."

h. The initials of the dispensing pharmacist.

8.14(2) The requirements of subrule 8.14(1) do not apply to unit dose dispensing systems, rule 8.9(155A,126); sterile products, rule 8.30(126,155A); and patient med paks, rule 8.13(155A,126).

657—8.15(155A) Records. When a pharmacist exercises the drug product selection prerogative pursuant to Iowa Code section 155A.32, the following information shall be noted:

8.15(1) Dispensing instructions by the prescriber or prescriber's agent shall be noted on the file copy of a prescription drug order which is orally communicated to the pharmacist.

8.15(2) The name, strength, and either the manufacturer's or distributor's name or the National Drug Code (NDC) of the actual drug product dispensed shall be placed on the file copy of the prescription drug order whether it is issued orally or in writing by the prescriber. This information shall also be indicated on the prescription in those instances where a generically equivalent drug is dispensed from a different manufacturer or distributor than was previously dispensed. This information may be placed upon patient medication records if such records are used to record refill information.

Rules 8.14(155A) and 8.15(155A) are intended to implement Iowa Code sections 155A.28, 155A.32, and 155A.35.

657—8.16(155A) Display of pharmacist license. Rescinded IAB 7/16/97, effective 8/20/97.

657—8.17(155A) Pharmacist temporary absence. Rescinded IAB 7/16/97, effective 8/20/97.

657—8.18(155A) Patient records.

8.18(1) A patient record system shall be maintained by all pharmacies for patients for whom prescription drug orders are dispensed. The patient record system shall provide for the immediate retrieval of information necessary for the dispensing pharmacist to identify previously dispensed drugs at the time a prescription drug order is presented for dispensing. The pharmacist shall be responsible for making a reasonable effort to obtain, record, and maintain the following information:

a. Full name of the patient for whom the drug is intended;

b. Address and telephone number of the patient;

c. Patient's age or date of birth;

d. Patient's gender;

e. Significant patient information including a list of all prescription drug orders obtained by the patient at the pharmacy maintaining the patient record during the two years immediately preceding the most recent entry showing the name of the drug or device, prescription number, name and strength of the drug, the quantity and date received, and the name of the prescriber; and

f. Pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.

8.18(2) The pharmacist shall be responsible for making a reasonable effort to obtain from the patient or the patient's caregiver, and shall be responsible for recording any known allergies, drug reactions, idiosyncrasies, and chronic conditions or disease states of the patient and the identity of any other drugs, including over-the-counter drugs, or devices currently being used by the patient which may relate to prospective drug review.

8.18(3) A patient record shall be maintained for a period of not less than two years from the date of the last entry in the profile record. This record may be a hard copy or a computerized form.

8.18(4) Information in the patient medication record shall be deemed to be confidential and may be released to the patient or the patient's authorized representative, the prescriber or other licensed practitioner then caring for the patient, another licensed pharmacist, the board or its representative, or any other person duly authorized by law to receive such information. Information in the patient medication record may be released to others only on written release of the patient.

657—8.19(155A) Prospective drug review. A pharmacist shall review the patient record and each prescription drug order presented for initial dispensing or refilling for purposes of promoting therapeutic appropriateness by identifying:

1. Overutilization or underutilization;
2. Therapeutic duplication;
3. Drug-disease contraindications;
4. Drug-drug interactions;
5. Incorrect drug dosage or duration of drug treatment;
6. Drug-allergy interactions;
7. Clinical abuse/misuse;
8. Drug-prescriber contraindications.

Upon recognizing any of the above, the pharmacist shall take appropriate steps to avoid or resolve the problem which shall, if necessary, include consultation with the prescriber. The review and assessment of patient records shall not be delegated to staff assistants other than pharmacist-interns.

657—8.20(155A) Patient counseling.

8.20(1) Upon receipt of a new prescription drug order and following a review of the patient's record, a pharmacist shall counsel each patient or patient's caregiver. The counseling shall be on matters which, in the pharmacist's professional judgment, will enhance or optimize drug therapy. Appropriate elements of patient counseling may include:

a. The name and description of the drug;

b. The dosage form, dose, route of administration, and duration of drug therapy;

c. Intended use of the drug, if known, and expected action;

d. Special directions and precautions for preparation, administration, and use by the patient;

e. Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;

f. Techniques for self-monitoring drug therapy;

g. Proper storage;

h. Prescription refill information;

i. Action to be taken in the event of a missed dose;

j. Pharmacist comments relevant to the individual's drug therapy including any other information peculiar to the specific patient or drug.

8.20(2) If in the pharmacist's professional judgment oral counseling is not practicable, the pharmacist may use alternative forms of patient information. Alternative forms of patient information may include written information leaflets, pictogram labels, video programs, or information generated by electronic data processing equipment. When used in place of oral counseling, alternative forms of patient information shall advise the patient or caregiver that the pharmacist may be contacted for consultation in person at the pharmacy by toll-free telephone or collect telephone call. A combination of oral counseling and alternative forms of counseling is encouraged.

8.20(3) Patient counseling, as described above, shall not be required for inpatients of a hospital or institution where other licensed health care professionals are authorized to administer the drugs.

8.20(4) A pharmacist shall not be required to counsel a patient or caregiver when the patient or caregiver refuses such consultation. A patient or caregiver's refusal of consultation shall be documented by the pharmacist. The absence of any record of a refusal of the pharmacist's attempt to counsel shall be presumed to signify that the offer was accepted and that counseling was provided.

657—8.21(155A) Skin puncture for patient training. A licensed pharmacist may perform skin puncture for purposes of training patients to withdraw their blood in order to perform self-assessment tests to monitor medical conditions including, but not limited to, diabetes. This does not preclude a pharmacist from performing venipuncture as authorized by institutional or clinic privileges.

657—8.22(155A) Blood pressure measurement. A licensed pharmacist may take a person's blood pressure and may inform the person of the results, render an opinion as to whether the reading is within a high, low, or normal range, and may advise the person to consult a physician of the person's choice.

657—8.23(155A) Compounding. Rescinded IAB 10/25/95, effective 1/1/96.

657—8.24(155A) Manufacturing. Rescinded IAB 10/25/95, effective 1/1/96.

Rules 8.18(155A) to 8.24(155A) are intended to implement Iowa Code sections 155A.11, 155A.13, 155A.17, 155A.35, 272C.2, and 272C.3.

657—8.25 to **8.28** Reserved.

657—8.29(155A,126) IV infusion products. Rescinded IAB 10/25/95, effective 1/1/96.

657—8.30(126,155A) Sterile products.

8.30(1) *Definitions.* For the purpose of this rule, the following definitions shall apply:

"Aseptic preparation" is the technique involving procedures designed to preclude contamination by microorganisms during processing.

"Batch preparation" is the compounding or repackaging of multiple units, in a single process, by the same operator.

"Class 100 condition" means an environment whose air particle count does not exceed a total of 100 particles of 0.5 microns and larger per cubic foot.

"Compounding" is the constitution, reconstitution, combination, dilution, or another process causing a change in the form, composition, or strength of any ingredient or any other attribute of a product.

"Critical area" is an area where sterilized products or containers are exposed to the environment during aseptic preparation.

"Hazardous drug" is a pharmaceutical that is antineoplastic, carcinogenic, mutagenic, or teratogenic.

"Home care patient" is a patient in the home environment or an institutionalized patient receiving products from a pharmacy located outside the institution.

"Repackaging" is the subdivision or transfer from a container or device into a different container or device.

"Sterile product" is a drug or nutritional substance free from living microorganisms that is compounded or repackaged by pharmacy personnel, using aseptic technique and other quality assurance procedures.

8.30(2) *Personnel.*

a. Pharmacist.

(1) Each pharmacy shall have a pharmacist responsible for supervising the preparation of IV infusion products compounded within the pharmacy.

(2) The pharmacist shall have the responsibility for admixture of infusion products, including education and training of personnel concerning proper aseptic technique, incompatibility, and provision of proper incompatibility information.

(3) When any part of these processes is not under direct pharmacy supervision, the pharmacist shall have the responsibility for providing written guidelines and for approving the procedures to ensure that all pharmaceutical requirements are met.

b. Pharmacy technicians.

(1) Pharmacy technicians shall receive documented on-the-job training and related education commensurate with the tasks they are to perform prior to the regular performance of those tasks.

(2) Pharmacy technicians shall receive regular and documented in-service education and training to supplement initial training.

(3) Pharmacy technicians shall understand and follow written policies and procedures for handling and preparing IV infusion products.

(4) Only technical functions can be performed by pharmacy technicians and only under the supervision of a pharmacist.

(5) A pharmacist shall ensure the accuracy of IV infusions prepared by pharmacy technicians prior to administration or dispensing to the patient.

8.30(3) *Reference requirements.* In addition to requirements set forth in rule 657—6.3(155A), 657—7.3(155A), 657—15.3(124,126,155A), or 657—16.5(155A), as appropriate, current copies of the following shall be maintained by all pharmacies involved in the preparation of IV infusion products:

a. American Hospital Formulary Service, Drug Information, with current supplements, or comparable type reference approved by the board.

b. Trissel's Handbook of Injectable Drugs or comparable type reference approved by the board.

8.30(4) *Policies and procedures.* A pharmacy providing sterile products shall prepare policies and procedures, evaluate them at least annually and revise them based on the evaluation, and maintain them in a manner that allows inspection by the board of pharmacy. Policies and procedures shall address, but not be limited to, the following:

a. Compounding, dispensing, and delivery of sterile products.

b. Quality assurance programs for the purpose of monitoring personnel qualifications, training, and performance.

c. Product integrity.

d. Equipment and facilities.

e. Guidelines regarding patient education.

8.30(5) *Labeling requirements.* At the time of delivery of the IV infusion product, the dispensing container shall bear a label with at least the following information:

a. The diluent.

b. Patient's name.

c. For home care patient prescriptions, prescription number or unique serial number.

d. Additive(s) name and quantity.

e. Date and time of preparation and pharmacist's initials. However, date and time may be omitted if this information can be documented elsewhere.

f. Stability (expiration) date and time (if pertinent) as set forth in the pharmacy's policy and procedure manual.

g. The prescribed flow rate in ml/hr, if applicable.

h. Ancillary labels as needed.

8.30(6) *Area to be set apart.* A pharmacy shall restrict entry into the area for preparing sterile products to designated personnel. The area shall be as follows:

a. Enclosed and structurally isolated from general work and storage areas.

b. Used only for the preparation of sterile products, hazardous drugs, or drugs requiring aseptic preparation.

c. Of sufficient size to allow pharmacists and other employees to work safely and accurately and to accommodate laminar airflow hoods as required.

8.30(7) *Additional equipment required.* The following additional equipment is required in a pharmacy preparing sterile products:

a. Laminar airflow hood or other devices capable of maintaining a critical area meeting Class 100 conditions during normal activity.

b. Disposal containers for hazardous drugs and wastes, including materials from patients' homes, if applicable.

c. Infusion devices, if needed.

d. Supplies and attire adequate to maintain an environment suitable for the aseptic preparation of sterile products.

e. Sufficient current reference materials related to sterile products to meet the needs of staff.

f. A sink with hot and cold running water for the purpose of hand scrubs, convenient to the area for preparing sterile products.

8.30(8) *Additional records required.* The pharmacy shall maintain records of lot numbers of the nonsterile components used in compounding sterile products.

8.30(9) *Environmental controls for sterile products.* The pharmacy shall ensure the environmental control of all sterile products in a manner that maintains sanitation, required storage temperatures, and exposure to light at the following times:

a. While products are held in the pharmacy.

b. When products are delivered to a patient.

c. During storage of products in the patient's home.

8.30(10) *Additional requirements for preparation of hazardous drugs.* The following additional requirements shall be met by pharmacies that prepare hazardous drugs:

a. All hazardous drugs shall be compounded in a vertical flow biological safety cabinet. Other product preparation may not be done concurrently in this cabinet.

b. Protective apparel shall be worn by personnel compounding hazardous drugs, including disposable gloves and gowns with tight cuffs.

c. Safety containment techniques for compounding hazardous drugs shall be used in conjunction with the aseptic techniques required for preparing sterile products.

d. Disposal of hazardous waste shall comply with applicable federal and state laws and regulations.

e. Written procedures for handling both major and minor spills of hazardous drugs shall be developed and maintained with the policies and procedures required in 8.30(4).

f. Prepared doses of hazardous drugs shall be dispensed and labeled with precautions inside and outside and shall be shipped in a manner to minimize the risk of accidental rupture of the primary container.

8.30(11) *Responsibilities for patient care.* If sterile products are provided to the patient in the home, the pharmacy and pharmacist have the following responsibilities:

a. The pharmacist shall be knowledgeable of the roles of the physician, patient, pharmacy, and home health care provider related to delivery of care and the monitoring of the patients.

b. The pharmacy shall have a pharmacist accessible at all times to respond to another health professional's and to a patient's questions and needs.

c. The pharmacist shall use the clinical and laboratory data of each patient to monitor initial and ongoing drug therapy. If the pharmacist does not have access to the data, the name of the health care provider assuming responsibility for monitoring drug therapy shall be documented in the patient's profile.

d. The pharmacist shall report to the prescribing physician any knowledge of unexpected or untoward response to drug therapy.

8.30(12) *Patient training.* If sterile products are provided to the patient in the home, the pharmacist shall verify the patient's or caregiver's training and competence in managing therapy. A pharmacist shall be involved, directly or indirectly, in training patients about drug compounding, labeling, storage, stability, or incompatibility. The pharmacist shall verify that the patient's or caregiver's competence is reassessed at intervals appropriate to the condition of the patient and type of drug therapy provided.

8.30(13) *Quality assurance.* A pharmacy shall have a documented, ongoing quality assurance control program to monitor personnel performance, equipment, and facilities which includes the following as a minimum:

a. Certification of all clean rooms and laminar airflow hoods by an independent contractor for operational efficiency at least annually with records of certification to be maintained for two years.

b. Written procedures requiring sampling if microbial contamination is suspected.

c. End-product testing, including tests for particulate matter and testing for pyrogens, which is documented prior to the release of the product from quarantine if batch preparation of sterile products is performed using nonsterile chemicals.

d. Written justification of the chosen expiration dates for compounded products.

e. Documentation of quality assurance audits at planned intervals based upon the needs of individual patients, including infection control and sterile technique audits.

f. Documentation that infusion devices being provided by the pharmacy for the administration of sterile products have received biomedical maintenance to provide for proper care, cleaning, and operation of the equipment.

This rule is intended to implement Iowa Code sections 126.10, 155A.2, 155A.4(2)*"f,"* 155A.13, 155A.13A, and 155A.28.

657—8.31(124,155A) Home health agency/hospice emergency drugs. Recognizing the emergency and unanticipated need for certain legend drugs to be available to qualified individuals authorized to administer drugs and employed by a home health agency or hospice, an Iowa-licensed pharmacy may provide certain medications pursuant to this rule. The emergency drug supply may be carried by such qualified individual.

8.31(1) *Contract.* A written contract shall exist between the home health agency or hospice and the pharmacist in charge of the Iowa-licensed pharmacy. This contract shall be available for review by the board or its authorized agent upon request.

8.31(2) *Ownership retained.* The legend drugs included in this emergency supply shall remain the property of and under the responsibility of the Iowa-licensed provider pharmacy.

a. The pharmacist shall ensure that each portable container of emergency drugs is sealed in such a manner that a tamperproof seal must be broken to gain access to the drugs.

b. Each portable container of emergency drugs shall be labeled on the outside of the container with a list of the contents and the earliest expiration date.

8.31(3) *Removal of medication.* All medications shall be administered only on prior prescribers' order or by protocol approved by the agency's medical director or appropriate committee. Medications administered from the emergency supply shall be replaced by submitting a prescription or medication order for the used item to the provider pharmacy within a reasonable time of administration.

8.31(4) *Records.* All records of medication administered from the emergency supply shall be maintained as required by law.

8.31(5) *Medications included.* The following emergency medications may be supplied by the pharmacy in sufficient but limited quantities. This list may be expanded only upon approval of the Iowa board of pharmacy examiners.

a. Heparin flush—pediatric (one strength);

b. Heparin flush—adult (one strength);

c. Sodium chloride for injection—small volume;

d. Epinephrine injection;

e. Diphenhydramine injection;

f. Corticosteroid injection;
g. Narcotic antagonist;
h. Urokinase for catheter care;
i. H_2 antagonist injection;
j. Nitroglycerin sublingual tablets;
k. Antinauseant agent.
l. Oral nonnarcotic analgesic;
m. Injectable nonnarcotic analgesic
n. Oral narcotic analgesic;
o. Oral antianxiety agent;
p. Injectable antianxiety agent; and
q. Oral sublingual anticholinergic agent.

If a container of an injectable product is opened and partially used, any unused portion shall immediately be discarded and appropriately documented.

8.31(6) *Policies and procedures.* The pharmacist in charge of the provider pharmacy and the home health agency or hospice shall develop policies and procedures to address storage conditions and security for medications and kit maintenance. Outdated, expired drugs shall be properly disposed of by the pharmacy.

8.31(7) *Responsibility for compliance.* The provider pharmacy is responsible to ensure compliance with this rule and any abuse or misuse of the intent of this rule shall be immediately reported to the board.

This rule is intended to implement Iowa Code sections 155A.13, 155A.15, and 155A.21.

657—8.32(124,155A) Emergency/first dose drug supply. In any facility which does not have an institutional pharmacy, drugs may be supplied for use by authorized personnel in one or more emergency/first dose drug supply containers located at such facility, provided that the emergency/first dose drug supply meets the requirements of this rule.

8.32(1) *Emergency/first dose drug supplies.* Only those emergency/first dose drugs determined by the provider pharmacist, as defined in subrule 8.32(2), the consultant pharmacist, the director of nursing of the facility, and the medical director of the facility, or their respective designees, as necessary for prompt use in patient care, may be made available in the emergency/first dose drug supply. Careful patient planning should be a cooperative effort between the pharmacy and the facility to make medications available, and this supply should only be used for emergency or unanticipated needs. The drugs in the emergency/first dose drug supply are the responsibility of the pharmacy and, therefore, shall not be used or altered in any way except as provided in this rule.

8.32(2) *Provider pharmacy/pharmacist.* All contents of the emergency/first dose drug supply will be provided by one pharmacy designated by the facility. This pharmacy shall be properly registered with the federal Drug Enforcement Administration (DEA) and the board and shall be currently licensed by the board.

8.32(3) *Medications included.* The provider pharmacist, as defined in subrule 8.32(2), the consultant pharmacist, the director of nursing of the facility, and the medical director of the facility, or their respective designees, shall jointly determine and prepare a list of medications, by identity and quantity, to be included in the emergency/first dose drug supply. Such list of medications shall be reviewed periodically per policy.

8.32(4) *Storage.* The emergency/first dose drug supply shall be stored in an area suitable to prevent unauthorized access and to ensure a proper environment for preservation of medications contained therein as required in official compendia. The provider pharmacist, as defined in subrule 8.32(2), is responsible for establishing procedures to maintain the security of the emergency/first dose drug supply.

8.32(5) *Labeling—exterior.* The exterior of an emergency/first dose drug supply shall be labeled clearly and shall unmistakably indicate that it is an emergency/first dose drug supply. Such label shall also contain a listing of the name, strength, and quantity of the drugs contained therein and an expiration date of the supply based upon the earliest expiration date of any drug contained in the supply.

8.32(6) *Labeling—interior.* All drugs contained in the emergency/first dose drug supply shall be labeled in accordance with subrule 8.3(2) or 8.9(3), as appropriate.

8.32(7) *Removal of medication.* Medication shall be removed from the emergency/first dose drug supply only pursuant to a valid prescription order and by authorized personnel or by the provider pharmacist. The provider pharmacy shall be notified that medication was administered to a specific patient prior to the administration of a second dose. Upon notification, the provider pharmacist shall perform drug use review to assess the appropriateness of drug therapy for the patient.

8.32(8) *Notifications.* Whenever an emergency/first dose drug supply is opened or has expired, the provider pharmacy shall be notified and the pharmacist shall be responsible for replacing the medication within 72 hours to prevent risk of harm to patients. Policy must be developed by the provider pharmacist to address notification, record keeping, and documentation procedures for use of the supply.

8.32(9) *Procedures.*

a. The consultant or provider pharmacist shall, in communication with the director of nursing of the facility and the medical director of the facility, or their respective designees, develop and implement written policies and procedures to ensure compliance with this rule.

b. The provider pharmacy shall keep a complete record of each controlled substance stored in the emergency/first dose drug supply and the number of doses provided.

c. The facility shall keep a complete record of the use of controlled substances from the emergency/first dose drug supply for two years, including the patient's name, the date of use, the name of the drug used, the strength of the drug, the number of doses used, the name of the prescriber authorizing the administration, and the initials of the person administering the dose.

8.32(10) *Penalty.* If any of the provisions of this rule are violated, the board may suspend, revoke, or otherwise discipline a pharmacy's license and a pharmacist's license and may modify, suspend, or revoke the controlled substances registrations of the pharmacy and the noncompliant facility.

[Filed 4/11/68; amended 11/14/73]
[Filed 11/24/76, Notice 10/20/76—published 12/15/76, effective 1/19/77]
[Filed 11/9/77, Notice 10/5/77—published 11/30/77, effective 1/4/78]
[Filed emergency 12/9/77—published 12/28/77, effective 12/9/77]
[Filed 10/20/78, Notice 8/9/78—published 11/15/78, effective 1/9/79]
[Filed 12/2/78, Notice 11/15/78—published 1/10/79, effective 2/14/79]
[Filed 12/21/78, Notice 11/15/78—published 1/10/79, effective 2/14/79]
[Filed 1/8/79, Notice 11/29/78—published 1/24/79, effective 2/28/79]
[Filed 8/28/79, Notice 5/30/79—published 9/19/79, effective 10/24/79]
[Filed 12/7/79, Notice 10/3/79—published 12/26/79, effective 1/30/80]
[Filed 2/22/80, Notice 10/3/79—published 3/19/80, effective 4/23/80]
[Filed emergency 4/22/80—published 5/14/80, effective 4/22/80]
[Filed 12/1/80, Notice 10/15/80—published 12/24/80, effective 1/28/81]
[Filed 2/12/81, Notice 12/24/80—published 3/4/81, effective 4/8/81]
[Filed 5/27/81, Notice 4/1/81—published 6/24/81, effective 7/29/81]
[Filed emergency 7/28/81—published 8/19/81, effective 8/1/81]
[Filed emergency 9/14/81—published 9/30/81, effective 9/30/81]
[Filed 7/28/82, Notice 3/17/82—published 8/18/82, effective 9/22/82]
[Filed emergency 8/26/82—published 9/15/82, effective 9/22/82]
[Filed 9/10/82, Notice 6/9/82—published 9/29/82, effective 11/8/82]
[Filed emergency 10/6/82—published 10/27/82, effective 10/27/82]◊
[Filed emergency 12/2/82—published 12/22/82, effective 12/22/82]
[Filed 11/18/83, Notice 8/3/83—published 12/7/83, effective 1/11/84]
[Filed 1/13/84, Notice 11/9/83—published 2/1/84, effective 3/7/84]
[Filed 6/22/84, Notice 4/11/84—published 7/18/84, effective 8/22/84]
[Filed emergency 7/13/84—published 8/1/84, effective 7/13/84]
[Filed 9/21/84, Notice 7/18/84—published 10/10/84, effective 11/14/84]
[Filed 2/22/85, Notice 11/21/84—published 3/13/85, effective 4/18/85]
[Filed emergency 6/18/85—published 7/3/85, effective 7/1/85]
[Filed 8/30/85, Notice 7/3/85—published 9/25/85, effective 10/30/85]◊
[Filed 11/27/85, Notice 8/28/85—published 12/18/85, effective 1/22/86]
[Filed 9/19/86, Notice 6/4/86—published 10/8/86, effective 11/12/86]
[Filed 1/28/87, Notice 11/19/86—published 2/25/87, effective 4/1/87]
[Filed emergency 1/21/88—published 2/10/88, effective 1/22/88]
[Filed 1/21/88, Notice 11/4/87—published 2/10/88, effective 3/16/88]
[Filed 3/29/88, Notice 1/27/88—published 4/20/88, effective 5/25/88]
[Filed 3/29/88, Notice 2/10/88—published 4/20/88, effective 5/25/88]
[Filed 11/17/88, Notice 8/24/88—published 12/14/88, effective 1/18/89]◊
[Filed emergency 5/16/89—published 6/14/89, effective 5/17/89]
[Filed 12/26/89, Notice 10/4/89—published 1/24/90, effective 2/28/90]
[Filed 3/19/90, Notice 1/10/90—published 4/18/90, effective 5/23/90]
[Filed 8/31/90, Notice 6/13/90—published 9/19/90, effective 10/24/90]
[Filed 1/29/91, Notice 6/13/90—published 2/20/91, effective 3/27/91]
[Filed 1/29/91, Notice 9/19/90—published 2/20/91, effective 3/27/91]
[Filed 4/26/91, Notice 2/20/91—published 5/15/91, effective 6/19/91]

◊Two ARCs

[Filed emergency 5/10/91—published 5/29/91, effective 5/10/91]
[Filed 7/30/91, Notice 5/29/91—published 8/21/91, effective 9/25/91]
[Filed 1/21/92, Notice 10/16/91—published 2/19/92, effective 3/25/92]
[Filed 3/12/92, Notice 1/8/92—published 4/1/92, effective 5/6/92]
[Filed 5/21/92, Notice 4/1/92—published 6/10/92, effective 7/15/92]
[Filed 10/22/92, Notice 9/2/92—published 11/11/92, effective 1/1/93]
[Filed 2/5/93, Notice 11/11/92—published 3/3/93, effective 4/8/93]
[Filed 9/23/93, Notice 5/26/93—published 10/13/93, effective 11/17/93]
[Filed 3/21/94, Notices 10/13/93, 12/8/93—published 4/13/94, effective 5/18/94]
[Filed 6/24/94, Notice 4/13/94—published 7/20/94, effective 8/24/94]
[Filed 11/30/94, Notices 5/11/94, 7/20/94—published 12/21/94, effective 1/25/95]
[Filed 3/22/95, Notice 11/9/94—published 4/12/95, effective 5/31/95]
[Filed 10/6/95, Notices 6/7/95, 8/16/95—published 10/25/95, effective 1/1/96]
[Filed emergency 12/14/95—published 1/3/96, effective 1/1/96]
[Filed 12/10/96, Notice 8/28/96—published 1/1/97, effective 2/5/97]
[Filed 2/27/97, Notice 8/28/96—published 3/26/97, effective 4/30/97]
[Filed 2/27/97, Notice 1/1/97—published 3/26/97, effective 4/30/97]
[Filed 6/23/97, Notice 3/26/97—published 7/16/97, effective 8/20/97]
[Filed 11/19/97, Notice 10/8/97—published 12/17/97, effective 1/21/98]